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Patent Application Serial No. 09/892,981 Amendment dated December 16, 2003 Reply to Office Action of October 16, 2003 Docket No. 01722906

## Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

## **Listing of Claims:**

- 1. (currently amended): A method for the treatment, prophylaxis, or reduction of the risk of developing a menopause disorder in a <u>female</u> mammal<u>ian subject</u> in need thereof, comprising: administering to the mammal a menopause disorder effective amount of methyltestosterone in an oral dosage unit, and at least one pharmaceutically acceptable steroid selected from the group consisting of estradiol, testosterone, androstenedione, androstenediol, dehydroepiandrosterone, prenenolone, and dihydrotestosterone, and enantiomers, isomers, prodrugs or salts of the same in a non-oral dosage unit
- (a) orally administering about 0.2 mg to about 50.0 mg of methyltestosterone or an enantiomer, isomer, prodrug, or salt of methyltestosterone; and
- (b) administering about 0.1 mg to about 100.0 mg of estradiol or an enantiomer, isomer, prodrug, or salt of estradiol.
  - 2. (canceled)
- 3. (previously amended): The method of claim 1, wherein the methyltestosterone is administered in the form of a tablet, capsule, cachet, lozenge, dispensable powder, granule, solution, suspension, emulsion or liquid.
  - 4-7 (canceled)
- 8. (currently amended): The method of claim 71, wherein the testosterone estradiol or an enantiomer, isomer, prodrug, or salt of estradiol is administered percutaneously.

- 9. (currently amended): The method of claim 87, wherein the testosterone estradiol or an enantiomer, isomer, prodrug, or salt of estradiol is administered in the form of a hydroalcoholic gel.
- 10. (original): The method of claim 9, wherein the hydroalcoholic gel further comprises at least one of a lower alcohol, a penetration enhancer, and a thickener.
- 11. (original): The method of claim 10, wherein the lower alcohol is selected from the group consisting ethanol, 2-propanol, and mixtures thereof.
  - 12. (original): The method of claim 10, wherein the enhancer is isopropyl myristate.
- 13. (previously amended): The method of claim 10, wherein the thickener is polyacrylic acid.
- 14. (currently amended): The method of claim 1, wherein the steroid is estradiol or an enantiomer, isomer, prodrug, or salt of estradiol is administered as a percutaneous gel formulation, the formulation comprising:
- (a) about 0.06% to about 10.0% estradiol or an enantiomer, isomer, prodrug, or salt of estradiol;
  - (b) about 0.1% to about 5.0% polyacrylic acid;
  - (c) about 0.1% to about 5.0% triethanolamine;
  - (d) about 30.0% to about 98.0% ethanol; and
  - (e) water in an amount sufficient to make the formulation 100%,
    wherein the percentages of components are weight to weight of the formulation.
  - 15-19 (canceled)
- 20. (currently amended): The method of claim 1, wherein the methyltestosterone or an enantiomer, isomer, prodrug, or salt of methyltestosterone and the steroid estradiol or an

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enantiomer, isomer, prodrug, or salt of estradiol are each provided as a separate component of a kit.

- 21. (original): The method of claim 1, wherein the mammal is a human.
- 22. (currently amended): The method of claim 1, wherein the methyltestosterone or an enantiomer, isomer, prodrug, or salt of methyltestosterone and the steroid estradiol or an enantiomer, isomer, prodrug, or salt of estradiol are administered in a sequential manner.
- 23. (currently amended): The method of claim 1, wherein the methyltestosterone or an enantiomer, isomer, prodrug, or salt of methyltestosterone and the steroid estradiol or an enantiomer, isomer, prodrug, or salt of estradiol are administered in a substantially simultaneous manner.

24-73 (canceled)